collected, until after the post-mortem examination is completed;

(4) Includes tables, benches, and other equipment on which sample collection and processing are to be performed, of such design, material, and construction as to enable sample collection and processing in a safe, ready, efficient, and clean manner;

(5) Has adequate arrangements, including liquid soap and cleansers, for cleansing and disinfecting hands, dissection tools, floors, and other articles and places that may be contaminated by diseased carcasses or otherwise; and

(6) Has adequate facilities, including denaturing materials, for the proper disposal in accordance with this chapter of tissue, blood, and other waste generated during test sample collection.

(c) The Administrator will give the operator of the establishment actual notice that APHIS, FSIS, or an APHIS contractor will be taking blood and/or tissue samples at the establishment. The Administrator may give the operator of the establishment notice in any form or by any means that the Administrator reasonably believes will reach the operator of the establishment prior to the start of sample collection.

(1) The notice will include the anticipated date and time sample collection will begin. The notice will also include the anticipated ending date and time.

(2) The Administrator will give the operator of the establishment as much advance notice as possible. However, the actual amount of notice will depend on the specific situation.

(d) *Denial and withdrawal of listing.* The Administrator may deny or withdraw the listing of an establishment upon a determination that the establishment is not in compliance with the requirements of this section.

(1) In the case of a denial, the operator of the establishment will be informed of the reasons for the denial and may appeal the decision in writing to the Administrator within 10 days after receiving notification of the denial. The appeal must include all of the facts and reasons upon which the person relies to show that the establishment was wrongfully denied listing. The Administrator will grant or deny the appeal in writing as promptly as circumstances permit, stating the reason for his or her decision. If there is a conflict as to any material fact, a hearing will be held to resolve the conflict. Rules of practice concerning the hearing will be adopted by the Administrator.

(2) In the case of withdrawal, before such action is taken, the operator of the establishment will be informed of the reasons for the proposed withdrawal. The operator of the establishment may appeal the proposed withdrawal in writing to the Administrator within 10 days after being informed of the reasons for the proposed withdrawal. The appeal must include all of the facts and reasons upon which the person relies to show that the reasons for the proposed withdrawal are incorrect or do not support the withdrawal of the listing. The Administrator will grant or deny the appeal in writing as promptly as circumstances permit, stating the reason for his or her decision. If there is a conflict as to any material fact, a hearing will be held to resolve the conflict. Rules of practice concerning the hearing will be adopted by the Administrator. However, withdrawal shall become effective pending final determination in the proceeding when the Administrator determines that such action is necessary to protect the public health, interest, or safety. Such withdrawal shall be effective upon oral or written notification, whichever is earlier, to the operator of the establishment. In the event of oral notification, written confirmation shall be given as promptly as circumstances allow. This withdrawal shall continue in effect pending the completion of the proceeding, and any judicial review thereof, unless otherwise ordered by the Administrator.

(Approved by the Office of Management and Budget under control numbers 0579–0212 and 0579–0342)

[69 FR 10150, Mar. 4, 2004, as amended at 78 FR 26489, May 7, 2013; 85 FR 4194, Jan. 24, 2020]

§ 71.22 Approval of laboratories to conduct official testing.

(a) *Approvals.* State, university, and private laboratories must obtain APHIS approval to conduct official testing for those diseases covered by

subchapters B, C, and D of this chapter. Laboratories seeking approval must meet the requirements of this section.

(b) *Facilities.* Official testing must be performed in laboratory facilities with controlled conditions, instrumentation appropriate for the testing being conducted, and biosecurity measures commensurate with the disease of diagnostic concern; each of these facility requirements must be acceptable to APHIS. Approved laboratories must agree to periodic, unannounced inspection by APHIS personnel or other APHIS-approved inspectors following an APHIS-approved checklist.

(c) *Quality system.* Laboratories must operate under a quality system acceptable to APHIS. Components of such systems include acceptable documentation of procedures, recordkeeping, training, reporting, and corrective actions taken if standards and procedures are not reached or maintained. Adherence to certain nationally or internationally established quality systems recognized by APHIS may be used to meet all or part of this requirement.[4] Quality system records are subject to review during facility inspections.

(d) *Procedures.* All official testing must be conducted using APHIS-approved assay methods,[5] which may include standard operating procedures recognized by the National Veterinary Services Laboratories (NVSL) or National Animal Health Laboratory Network, and/or diagnostic test kits licensed by the USDA.

(e) *Training.* Official testing must be conducted only by those individuals who have completed APHIS-approved training and have passed proficiency tests administered by APHIS or its official designee. These tests will be administered annually or as necessary at an interval stipulated by APHIS. Supervisory oversight of official testing must be performed by qualified individuals, as determined by APHIS.

(f) *Reporting.* Approved laboratories must report test results to APHIS and State animal health officials using an individualized (by disease) timeline established by APHIS at the time of laboratory approval.

(g) *Applications for approval.* (1) Laboratories must use APHIS application forms, including an agreement to meet the obligations to APHIS listed in this section, and submit completed forms to the NVSL Director. The Director will make a preliminary determination of the application's acceptability, based on initial review of submitted materials and, when appropriate, a needs assessment for diagnostic capacity. These determinations are made on an annual basis, or as needed based on the number of applications received.

(2) Applicants will be informed of the preliminary determination. If positive, applicants will then be able to request a facility inspection and personnel training, conducted in accordance with this section. If negative, APHIS will provide a rationale for the denial. Denied applicants may appeal any denials in accordance with the regulations in paragraph (j) of this section;

(3) When all requirements in this section have been met, the NVSL Director will issue a final approval. Approvals are specific to those lab personnel working at the inspected, approved laboratory who have met the eligibility and proficiency requirements. Denied applicants may appeal any denials in accordance with the regulations in paragraph (j) of this section.

(h) *Maintenance of approved status.* (1) Previously approved laboratories that wish to maintain their approved status must reapply for APHIS approval at least 1 month before their approval term expires, or at least every 2 years, whichever comes first. Laboratories wishing to maintain approved status must submit a renewal application form, as supplied by APHIS, to the NVSL Director.

(2) Approved laboratories must have at least one individual with the required training and unexpired proficiency certification in their employ at all times.

(3) Approved laboratories must perform the minimum number of tests to maintain proficiency, as stipulated by

[4] A list of established quality systems recognized by APHIS is available on the internet at *https://www.nahln.org.*

[5] A list of approved assay methods is available on the APHIS Laboratory Portal website at *https://www.nahln.org* and at *https://www.aphis.usda.gov/aphis/ ourfocus/ animalhealth/ animal-disease-information.*

APHIS in the guidance documents developed for individual test types.

(i) *Probation, suspension, and rescission of laboratory approval.* (1) Laboratories not conducting the minimum number of tests as required by paragraph (h)(3) of this section during a single reporting period will be assigned probationary status. A reporting period is less than or equal to the time for which the laboratory has been approved to conduct testing by APHIS. Laboratories on probation may continue to conduct official testing. If the minimum required number of tests are not performed during two consecutive reporting periods, the laboratory will not be eligible for renewal of APHIS approval. Exceptions to this requirement may be granted by the NVSL Director upon request.

(2) Approval to conduct official testing will be suspended in the event that a laboratory experiences changes that may impact its ability to provide quality testing services. These changes include: No longer employing an individual approved to conduct official testing, a move to different facilities, or a natural disaster that impacts power or water systems. Laboratories with suspended status will not be approved to conduct official testing. Laboratories will be restored to approved status upon training and/or testing new personnel, successful inspection of new facilities, and/or correction of noncompliance issues. Reapproval will involve resubmitting those sections of the application materials required by the NVSL Director.

(3) Approval may be rescinded at any time, at the discretion of the NVSL Director, if a laboratory fails to meet its obligations to APHIS, as listed in the agreement signed by the laboratory during the application process. The NVSL Director will issue a notice to the laboratory, providing the justification for the proposed removal. Laboratories will have 30 days to respond in writing to the concerns provided before the NVSL Director finalizes the removal decision.

(j) *Appeals.* Appeal of any denial, probation, suspension, or rescission of laboratory approval must be made in writing to the APHIS Administrator or the Administrator's official designee within 30 days of the laboratory's receipt of the NVSL Director's decision. Responses to these appeals will be provided within 60 days of receipt by APHIS.

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[85 FR 4194, Jan. 24, 2020]

PART 72—BOVINE BABESIOSIS

Sec.